MAINE BUREAU OF HEALTH
INSTITUTIONAL REVIEW BOARD (IRB)
REQUEST FOR CONTINUATION APPROVAL OF PROTOCOL

Instructions: Use this form when submitting protocols for continuing review. Review is required AT LEAST annually; however, the IRB may have determined that your protocol will need to be reviewed more often. Please submit this form along with the current consent form and a copy of the protocol (if changed since last year) and any supporting documents (if changed since last year) to the IRB Chairperson. Consecutively number all pages, beginning with the title page of the protocol (if applicable), followed by any consent form(s) and any applicable ancillary documents. Complete all applicable items or the form will be returned.

Date Submitted by Investigator:

PROTOCOL NO. _____ Date Rec'd MBOH IRB

(For Human Subjects Office Use)

Title of Protocol:

Proposed Dates for Project - Begin:: _____ End:

Name of MBOH Employee Serving as Principal Investigator (PI) and Degrees:

_____

Telephone.: _____

Email Address: _____

Names of Other MBOH Employee Co-investigators (use supplemental page if > than 3):

1.

2.

3.

1. Current Status

_____ Study not yet begun (Provide explanation in item 4. Complete item 6, if applicable)

_____ Active research; contact with subjects continuing (Complete items 2-9)

_____ Active research with subjects completed; study activities involve only data analysis and/or report writing (Complete items 2,5,6,7,9)

_____ Study does not involve contact with subjects (e.g., research using existing records); study activities involve only data analysis and/or report writing (Complete items 5,6,7,9)

2. Study Population

_____ Enrolled this past year

_____ Declined enrollment this past year

_____ Total number of subjects to date

_____ Withdrawn from project this past year

For individuals who were enrolled this year:
Gender distribution:
_____ % Female
_____ % Male

Race/ethnicity distribution of enrolled subjects for domestic studies:

_____ % American Indian or Alaskan Native
_____ % Asian or Pacific Islander
_____ % Black or African American, not of Hispanic origin
_____ % Hispanic
_____ % White, not of Hispanic Origin

If an international study, provide race/ethnicity of subjects by percentages:

Vulnerable Populations - Have any of these populations been added to the study? _____ YES _____ NO
If YES, please check all that apply

_____ Pregnant women (as a SPECIFIC target group)
_____ Fetuses (Ref: 45CFR46, Subpart B)
_____ Prisoners (Ref: 45CFR46, Subpart C)
_____ Children 17 years of age or younger (Ref: 45CFR46, Subpart D)
_____ Mentally disabled
_____ Educationally or economically disadvantaged

3. Collaborating Sites (Use additional sheets if necessary)

3a. List any collaborating sites by name and location (including state) that were added since last continuation approval:

_____ None added

	OPRR Assurance No.:
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	

3b. List any collaborating sites by name and location (including state) that were deleted since last continuation approval:

_____ None deleted

1.

2.

3.

4.

5.

6.

7.

8.

4. FUNDING (check one)

_____ Funding Mechanism Used:

- _____ Cooperative Agreement No(s).:
- _____ Contract No(s).:
- _____ Grant:
- _____ Purchase Order (a.k.a. Simplified Acquisition):

_____ Other funding mechanism:

- _____ Memorandum of Understanding (MOU) (With whom):
- _____ Interagency Agreement (IAA) (Name of other agency):
- _____ Other (Specify type and with whom):

_____ Only **MBOH** investigators performing study

_____ Collaborative (Non-**MBOH** investigators & **MBOH** investigators; no funding involved)

5. Summary of Activities to Date (Use additional sheets as necessary):

6. Summary of Study Modifications Reviewed and Approved This Past Year (Use additional sheets as necessary):
_____ None

7. Summary of Any New Literature, Findings, or Other Relevant Information (Use addition sheets as necessary):
_____ None

8. **Summary of Adverse Events or Unanticipated Problems** (Use additional sheets as necessary):
_____ None

9. Consent Documents (Attach a copy of each current consent form, telephone consent text, and/or consent letter):

10. Summary of Remaining Activities (Use additional sheets as necessary):

Approvals (Signature and Position Title): Program Manager:	**Date:**	**Remarks:**
Division Director:		
MBOH IRB Chairperson:		

MAINE BUREAU OF HEALTH
INSTITUTIONAL REVIEW BOARD (IRB)
REQUEST FOR AMENDMENT APPROVAL OF PROTOCOL

Instructions: Use this form to submit any changes to your research. Please submit this form along with a copy of the protocol, current consent form, and any supporting documents to the IRB Chairperson. Consecutively number all pages, beginning with the title page of the protocol, followed by any consent form(s) and ancillary documents. Complete all applicable items or the form will be returned.

Date Submitted by Investigator:

PROTOCOL NO.
Date Rec'd IRB

(For IRB Office Use)

Title of Protocol:

Proposed Dates for Project - Begin: _____ End:

Name of MBOH Employee Serving as Principal Investigator (PI) and Degrees:

Telephone.:

Email Address:

Names of Other MBOH Employee Co-investigators (use supplemental page if > than 3):

1.

2. _____

3. _____

1. FUNDING (check one)

_____ Funding Mechanism Used:

- _____ Cooperative Agreement No(s).:
- _____ Contract No(s).:
- _____ Grant:
- _____ Purchase Order (a.k.a. Simplified Acquisition):

_____ Other funding mechanism:

- _____ Memorandum of Understanding (MOU) (With whom):
- _____ Interagency Agreement (IAA) (Name of other agency):
- _____ Other (Specify type and with whom):

_____ Only MBOH investigators performing study

_____ Collaborative (Non-MBOH investigators & MBOH investigators; no funding involved)

2. Collaborating Sites (Use additional sheets if necessary)

2a. List any collaborating sites by name and location (including state) that were added since last approval:

_____ None added	**OPRR Assurance No.**
1.	
2.	
3.	
4.	
5.	

2b. List any collaborating sites by name and location (including state) that were deleted since last approval:

_____ None deleted

1.

2.

3.

4.

5.

3. Description of proposed modification(s) to the protocol:

4. Reasons for proposed modification(s):

Approvals (Signature and Position Title): Program Manager:	**Date:**	**Remarks:**
Division Director:		
IRB Chairperson:		

INSTITUTIONAL REVIEW BOARD (IRB)
REQUEST FOR TERMINATION OF PROTOCOL

Instructions: Use this form when terminating (completed/withdrawn/canceled) a protocol. Please submit this form to the IRB Chairperson. Complete all applicable items or the form will be returned.

Date Submitted by Investigator:

PROTOCOL NO.
Date Rec'd

(For IRBs Office Use)

Title of Protocol:

Name of MBOH Employee Serving as Principal Investigator (PI) and Degrees:

Telephone.:
Email Address:

1. Current status:

_____ CANCELED (Never started) (Attach explanation)
_____ COMPLETED (Complete items 2,3,4)

2. Disposition of Data:

_____ Original data and/or research materials have been destroyed
_____ Linkage between existing data and original source of information has been destroyed. No individuals can be identified from existing data.
_____ Data with identifiers or linkage will be retained. Indicate:
Why:

Where:

How long:

3. Study Population

_____ Enrolled this past year
_____ Declined enrollment this past year
_____ Total number of subjects to date
_____ Withdrawn from project this past year

For individuals who were enrolled this year:
Gender distribution:
_____ % Female
_____ % Male

Race/ethnicity distribution of enrolled subjects for domestic studies:
_____ % American Indian or Alaskan Native
_____ % Asian or Pacific Islander
_____ % Black or African American, not of Hispanic origin
_____ % Hispanic
_____ % White, not of Hispanic Origin

If an international study, provide race/ethnicity of subjects by percentages:

4. Final Report (Attach a copy of the final report for a completed study)

Approvals (Signature and Position Title): Program Manager:	**Date:**	**Remarks:**
Division Director:		
IRB Chairperson:		